3EC International a.s., Hranicna 18, 821 05 Bratislava, Slovakia
SKTC-113 and Notified Body No. 2265

EC CERTIFICATE

No. 2011-MDD-021

issued in compliance wirh the Council Directive 93/42/EEC as amended 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 (Collection of Laws), certifies that the medical devices of Class IIb,

SYRINGE PUMP
Plenum - ASPIRE Syringe Micro Infusion System,
Plenum - Zion Syringe Micro Infusion System,
Plenum - Zion Plus Syringe Micro Infusion System
Registered trade mark; Plenumtek®

manufactured by company

Plenum Tech Pvt. Ltd.

'Riddhi-Siddhi', Plot No. 141, Shilpa Co. Hsg. Society,Opp. Lane to Ajanta Marbles,
Manishnagar, Somalwada, Nagpur-440015, Maharashtra
INDIA

are manufactured under conditions fulfilling the quslity system requirements of Annex II, Section 3.2, of rhe Directive93/42/EEC as amended2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed,approved and is subject to continuous surveillance accordingto AnnexII, Sections 3.3,and 5,of the Directive 93/42/EEC as amended 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Final protocol No.32/2016 that is enclosed to this certificate.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced models of medical device and it does not substitute the design or type- examination procedures , if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until the July 6th, 2021 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits. After fulfilling the relevant EU legislation requirements,the manufacturer shall affix to each medical device of the above referenced models, the CE marking followed by the number of the Notified Body.

At.Bratislava, on July 7th, 2016

Notified body
3EC international
NB 2265
NOTIFIKOVANA OSOBA

Dr. Katarina Srdosova
Responsible to act on behalf of NB 2265

FOR SHREYA ENTERPRISES
Proprietor/Authorised Signatory

3EC International a.s., Hranicna 18, 821 05 Bratislava, Slovakia

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FINAL PROTOCOL OF PRODUCT CONFORMITY ASSESSMENT

Protocol No.: 32/2016

Product:	**Syringe Pump**
Model / Type:	**Plenum – ASPIRE Syringe Micro Infusion System, Plenum – Zion Syringe Micro Infusion System, Plenum – Zion Plus Syringe Micro Infusion System**
Registered trade mark:	Plenumtek®
Manufacturer: *(name & address)*	**Plenum Tech Pvt. Ltd. 'Riddhi-Siddhi', Plot No. 141, Shilpa Co. Hsg. Society, Opp. Lane to Ajanta Marbles, Manishnagar, Somalwada, Nagpur-440015, Maharashtra, INDIA** VAT No.: 2723017999V
Applicant: *(name & address)*	**Plenum Tech Pvt. Ltd. 'Riddhi-Siddhi', Plot No. 141, Shilpa Co. Hsg. Society, Opp. Lane to Ajanta Marbles, Manishnagar, Somalwada, Nagpur-440015, Maharashtra, INDIA** VAT No.: 2723017999V
Ref. No. (Application No.):	320042/2016
Assessed by: **Issued on:**	Dr. Mark Tomin 7th July, 2017
Distribution List:	1x – Applicant 1x – 3EC International a.s.

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For SERBYA ENTERPRISES
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1. INTRODUCTION

This final report is based on the manufacturer's application No. 320042/2016 dated May 12th, 2016 for conformity assessment of Class IIb medical devices pursuant to act of the Parliament of the Slovak Republic No. 264/1999 (Collection of Laws) on technical requirements and on conformity assessment as amended and the Council Directive 93/42/EEC as amended by 2007/47/EC, on conformity assessment of medical devices.

The aim of this assessment is to demonstrate the fulfillment of the safety requirements specified by the European law and to facilitate placing of the certified products to the EU market.

2. PRODUCT SPECIFICATION

The certified products, medical devices – Syringe Pumps - have been placed on the Indian market since year 2009.

The medical devices were assessed from the following aspects:

- Essential Safety Requirements
- Applied standards and regulations
- Risk Analysis
- Clinical Evaluation
- Audit Report

2.1. Intended Use of the Products

The certified products, medical devices – Syringe Pumps (Syringe Micro Infusion Systems) are manufactured in three variants: Plenum – ASPIRE Syringe Micro Infusion System, Plenum – Zion Syringe Micro Infusion System, Plenum – Zion Plus Syringe Micro Infusion System. Comparison of the models is given in the Table below.

The Plenum's ASPIRE / Zion / Zion Plus Syringe Micro Infusion Pumps are designed to infuse the drug into the vascular system of humans. Each machine is accomplished with microprocessor control of flow rate & volume, activates alarms automatically if the infusion rate cannot be maintained or the solution runs out – all provided by a motor – driven mechanism.

Description	**ASPIRE** Syringe Micro Infusion System	**Zion** Syringe Micro Infusion System	**Zion Plus** Syringe Micro Infusion System
Display	7 Segment LCD Display	128x 64 pixel Graphic LCD	128 x 64 Pixel Graphic LCD
Rate (ml/hr)	0.1 to 999.9	0.1 to 1200	0.1 to 2000
Bolus	0.1 to 999.9	0.1 to 1200	0.1 to 2000
Bolus rate	Factory preset	Settable (0.1 to 1200)	Settable (0.1 to 2000)
Occlusion	Three level factory preset	Option Three level factory present Selectable from 100 to 1200 mmHg in Steps of 50 mm Hg	Option Three level factory present Selectable from 100 to 1200 mmHg in Steps of 50 mm Hg
KVO	0.1 ml/hr or 1% of the set rate which ever is higher	0.1 ml/hr or 1% of the set rate which ever is higher	0.1 ml/hr or 1% of the set rate which ever is higher
KVO Enable/ Disable	--	Facility to enable/ disable	Facility to enable/ disable
Drug Library	Not availalble	Available	Available

2.2. Medical Devices Classification

The certified products have been classified by the manufacturer according to the Annex IX of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC as Class IIb medical devices. The products are active devices intended to administer medicines or other substances to or from the

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body for which Rule 11 shall be applied.

2.3. List of Documents and Testing Reports Applied in the Conformity Assessment Process

The technical file lodged complies with requirements of the Council Directive 93/42/EEC as amended and the Slovak Government Decree No. 582/2008 Coll. stated in Annexes II and contains the following documents:

Applicationon Conformity Assessment No. 320042/2016 , Dated May 12th, 2016
Technical File for Syringe Pump: Plenum - ASPIRE Syringe Micro Infusion System; Plenum - Zion Syringe Micro Infusion System; Plenum – Zion PLus Syringe Micro Infusion System; Doc. No. TF01; Rev. No. 01; Rev. Date: 04/08/2011
Essential Safety Requirements; Doc. No. PTPL/ESR/ Plenum – ASPIRE, Zion, Zion Plus Syringe Micro Infusion System; Rev. No. 00; Date: 15/11/2010
Risk Assessment of Plenum – ASPIRE Syringe Micro Infusion System; Rev. 01; Date: 04/08/2011; Risk analysis as per EN ISO 14971:2009
Risk Assessment of Plenum – Zion Syringe Micro Infusion System; Rev Rev. 01; Date: 04/08/2011; Risk analysis as per EN ISO 14971:2009
Risk Assessment of Plenum – Zion PLus Syringe Micro Infusion System; Rev. 01; Date: 04/08/2011; Risk analysis as per EN ISO 14971:2009
Test Report No.1104025 (IEC 60601-1); Tested Sample: Syringe Pump / ASPIRE; Date of Issue: 05/04/2011; Tested by: National Electrical & Electronic Laboratory (West), Pune, India
Test Report No. 1104004 (IEC 60601-1-2:2007); Tested Sample: Syringe Pump / ASPIRE; Date of Issue: 05/04/2011; Tested by: National Electrical & Electronic Laboratory (West), Pune, India
Test Report No. ST/11/05/01 (IEC 60601-2-24:1998); Tested Sample: Syringe Pump / ASPIRE; Date of Issue: 10/05/2011; Tested by: Safe Tek Laboratory, Pune, India
Software Validation Summary Report (IEC 60601-1-4) of Medical device Plenum – ASPIRE Syringe Micro Infusion System; in-house report; Rev. 01; Date: 04/08/2011
Software Validation Summary Report (IEC 60601-1-4) of Medical device Plenum – Zion Syringe Micro Infusion System; in-house report; Rev. 01; Date: 04/08/2011
Software Validation Summary Report (IEC 60601-1-4) of Medical device Plenum – Zion Plus Syringe Micro Infusion System; in-house report; Date: Rev. 01; Date: 04/08/2011
Operating Manual; Plenum ASPIRESyringe Micro Infusion System; Rev. No.: 00; Date of Issue: 15/11/2010
Operating Manual; Plenum Zion Syringe Micro Infusion System; Rev.No.: 00; Date of Issue: 15/11/2010
Operating Manual; Plenum Zion Plus Syringe Micro Infusion System; Rev. No.: 00; Date of Issue: 15/11/2010
Draft Label (ASPIRE / Zion/ Zion Plus Syringe Micro Infusion System)
QMS ISO 9001: 2008 Certificate No. A091W11844; Scope: Design, manufacturing & sale of medical devices for infusion therapy; Issued by: BMQR Certifications Pvt., Ptd., India; Valid until: 16/03/2014
QMS ISO 13485:2003 Certificate No. A091W11841; Design, manufacturing & sale of medical devices for infusion therapy; Issued by: BMQR Certifications Pvt., Ptd., India; Valid until: 16/03/2014
EC Declarations of Conformity; Plenum – ASPIRE / Zion / Zion Plus Syringe Micro Infusion System; Date: 15/11/2010
Audit Report on assessment of Medical Device Manufacturer's Quality Management System according to Annex II MDD 93/42 /EEC as amended in compliance with the harmonized European standard EN ISO 13485:2003, Dated June 16, 2016
Clinical Evaluation: Plenum ASPIRE Syringe Micro Infusion System; Rev. 01; Date: 04/08/2011
Clinical Evaluation: Plenum Zion Syringe Micro Infusion System; Rev. 01; Date: 04/08/2011
Clinical Evaluation: Plenum Zion Plus Syringe Micro Infusion System; Rev. 01; Date: 04/08/2011

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3. CONCLUSIONS FROM CONFORMITY ASSESSMENT

3.1. Chosen Conformity Assessment Procedure

The Class IIb medical devices were subjected to conformity assessment procedures described in Article 11 (3), letter a, that are based on the procedure of Annex II (Full Quality Assurance), excluding the point 4 of the Annex II.

3.2. Essential Safety Requirements

The document of Essential Safety Requirements elaborated by the manufacturer declares fulfillment of the essential requirements in required range related to the assessed medical devices classified as the Class IIb in compliance to Annex IX of the Council Directive 93/42/EEC as amended by 2007/47/EC.

The requirements of the mentioned Council Directive 93/42/EEC as amended by 2007/47/EC are equivalent to the Slovak Government Decree No. 582/2008 Coll. Conformity to this Government Decree means also the conformity to the appropriate Directive and vice versa.

3.3. Applicable Standards and Regulations

In case of existing harmonized European standards, the compliance to the harmonized EN standards gives a presumption of conformity. The declared application of harmonized standards and other technical specifications is in compliance with the essential requirements of the above mentioned directive related to the certified product:

- EN 980:2008; Graphical symbols for use in the labeling of medical devices
- 93/42/EEC as amended by 2007/47/EC; Council Directive on Medical Devices as amended
- ISO 9001:2008; Quality management systems. Requirements
- EN ISO 13485:2003/AC:2007; Medical Devices Quality Management System
- EN 1041:2008; Information supplied by the manufacturer of medical devices;
- EN ISO 14971:2009; Medical Devices - Application of risk management to medical devices
- EN 45014:1998; General criteria for supplier's declaration of conformity
- EN 62366:2008; Medical devices. Application of usability engineering to medical devices
- IEC 60601-1-1:2006; Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2:2007; Medical electrical equipment -- Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4:1996; Medical electrical equipment -- Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems
- IEC 60601-2-24:1998; Medical electrical equipment -- Part 2-24: Particular requirements for the safety of infusion pumps and controllers

3.4. Risk Analysis

Risk Analysis was performed in accordance with EN ISO 14971:2009. The analysis reports are detailed and meet the risk level for the assessed Class IIb medical devices. The Risk Analysis for artech ion detox (electrolysis system) specifies identification of hazards associated with the product; identifies methods to control these risks and how to monitor effectiveness of the controls in compliance with EN ISO 14971:2009. The risk management process applies to all stages of the life-cycle of the certified medical device including design/product realization and through marketing and distribution.

3.5. Clinical Evaluation

The medical devices are safe to patients, doctors and hospital staff if used in accordance with

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defined intended use and as mentioned in the Operational Manuals.

3.6. Assessment of the manufacturer's quality system

The manufacturer's quality system assessment has been carried out by the examination of the documentation and the certification audit performed at the manufacturer's premises pursuant to requirements of Annex II (excl. point 4) of the Council Directive 93/42/EEC as amended by 2007/47/EC. The conclusions of assessment are stated in the Audit Report dated June 16th, 2016. The results confirmed the manufacturer's quality system fulfills requirements of the Directive 93/42/EEC as amended by 2007/47/EC as well as the Slovak Government Decree No. 582/2008 Coll., on technical requirements and conformity assessment routes for medical devices. The manufacturer's quality system related to the above mentioned medical devices has been created and satisfactorily documented according to harmonized standard ISO 13485:2003.

4. CONCLUSIONS

The conformity assessment of medical devices and their evaluation described in Section 3 of this report demonstrates compliance of the product properties with the technical requirements applied to it. Medical devices can be distributed and used in healthcare facilities of the Slovak Republic as well as in the European Union Member States and must be affixed with the CE marking of conformity pursuant to the Council Directive 93/42/EEC as amended by 2007/47/EC, Annex XII and the Slovak Government Decree No. 582/2008 Coll.

In accordance to the aforementioned findings the Notified Body No. 2265 issues for the medical devices

SYRINGE PUMP
Plenum – ASPIRE Syringe Micro Infusion System,
Plenum – Zion Syringe Micro Infusion System,
Plenum – Zion Plus Syringe Micro Infusion System
Registered trade mark: Plenumtek®

EC Certificate in accordance with Annex II (excl. point 4) of the Council Directive 93/42/EEC as amended by 2007/47/EC that is implemented by the Slovak Government Decree No. 582/2008 Coll. – the manufacturer applies a quality system ensuring conformance of the assessed products with the provisions of the Council Directive No. 93/42/EEC (MDD) as amended by 2007/47/EC which apply to them.

The validity of the certificate is five (5) years and is conditional upon positive results of regular surveillance audits of the approved quality system by the Notified Body No. 2265 in the meaning of the Council Directive 93/42/EEC as amended by 2007/47/EC and the Slovak Government Decree No. 582/2008 Coll.

After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced model, the CE marking followed by the number of the Notified Body.